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Date of Deposit September 30, 1999.

REQUEST FOR FILING A CONTINUING PATENT APPLICATION UNDER 37 CFR § 1.53(b)(1)

Case No.	ANTICIPATED CLASSIFICATION OF THIS APPLICATION		PRIOR APPLICATION EXAMINER	ART UNIT
6298/308	CLASS 128	SUBCLASS 200.220	A. Lewis	3761

Address to:

Assistant Commissioner for Patents
Washington, DC 20231

This is a request for filing a ☒ continuation ☐ divisional application under 37 CFR § 1.53(b)(1), of pending prior application number 08/842,956, filed on April 25, 1997, entitled EXHALATION VALVE FOR FACE MASK WITH SPACER CHAMBER CONNECTION, claiming priority of U.S. Serial No. 08/270,752, filed on July 5, 1994.

- ☒ Copy of the Prior application, including 21 pages of Application, which includes two sheets of drawings as filed with application number 08/842,956.
- ☒ Two (2) new sheets of formal drawings are enclosed (Figs. 1-12).
- ☒ Copy of the Declaration filed in the Prior applications.
- ☒ Information Disclosure Statement and copies of Information Disclosure Statement and Examiner-Initialed PTO Form 1449 previously filed in 08/842,956.

CLAIMS	(1) FOR	(2) NUMBER FILED	(3) NUMBER EXTRA	(4) RATE	(5) CALCULATIONS
	TOTAL CLAIMS (37 CFR 1.16(c))	28 - 20 =	8	x \$ 18 =	\$144
	INDEPENDENT CLAIMS (37 CFR 1.16(b))	9 - 3 =	6	x \$ 78 =	\$468
	MULTIPLE DEPENDENT CLAIMS (if applicable) (37 CFR 1.16(d))			+ \$260 =	\$
				BASIC FEE (37 CFR 1.16(a))	\$760
				Total of above Calculations =	\$
	Reduction by 50% for filing by small entity (Note 37 CFR 1.9, 1.27, 1.28)				\$
				TOTAL =	\$1,372.00

- ☐ A verified statement to establish small entity status under 37 CFR 1.9 and 1.27
☐ is enclosed.
☐ was filed in prior application number _____ and such status is still proper and desired (37 CFR 1.28(a)).
- ☒ The Assistant Commissioner is hereby authorized to charge any fees which may be required under 37 CFR 1.16 and 1.17, or credit any overpayment to Deposit Account No. 23-1925. A duplicate copy of this sheet is enclosed.
- ☒ Enclosed is a check for \$1,372.00 to cover the filing fees.
- ☐ Cancel in this application original claims 16-27, 30 and 31 of the prior application and otherwise enter the attached preliminary amendment before calculating the filing fee. (At least one original independent claim must be retained for filing purposes).
- ☒ The inventors of the invention being claimed in this application are: MARTIN P. FOLEY and ROBERT MORTON.

10. ☐ This application is being filed by less than all the inventors named in the prior application. In accordance with 37 CFR 1.63(d)(2), the Assistant Commissioner is requested to delete the name(s) of the following person or persons who are not inventors of the invention being claimed in this application: _____.
11. ☒ Amend the specification by inserting before the first line the sentence: "This application is a ☒ continuation ☐ division of application number 08/842,956, filed April 25, 1997, (pending), claiming priority of U.S. Serial No. 08/270,752, filed on July 5, 1994, which applications are hereby incorporated by reference."
12. ☐ Priority of foreign application number _____, filed on _____ in _____ is claimed under 35 U.S.C. 119.
☐ The certified copy has been filed in prior application number _____, filed _____.
13. ☒ A preliminary amendment is enclosed.
14. ☒ The prior application is assigned of record to Trudell Medical Limited.
15. ☐ Also enclosed: _____.
16. ☐ The power of attorney in the prior application is to: _
a. ☐ The power appears in the original papers in the prior application.
b. ☐ Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
c. ☒ Address all future correspondence to: (may only be completed by applicant, or attorney or agent of record.)

September 30, 1999
Date

Vita G. Conforti
BRINKS HOFER GILSON & LIONE
P.O. BOX 10395
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Signature
Name: Vita G. Conforti
Reg. No. 39,639

- ☐ Inventor(s)
☐ Assignee of complete interest
☒ Attorney or agent of record
☐ Filed under 37 CFR 1.34(a)
Registration Number if acting under 37 CFR 1.34(a): _____.

EXPRESS MAIL NO.: EL402612973US

DATE OF MAILING: September 30, 1999

Our Case No. 6298/308

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application Of:)	
FOLEY ET. AL.)	Previously-
)	Assigned Examiner: A. Lewis
Serial No.: Not Yet Assigned)	
)	Previously-Assigned
Filing Date: Herewith)	Group Art Unit No.: 3761
)	
FOR: EXHALATION VALVE FOR FACE MASK)	
WITH SPACER CHAMBER CONNECTION)	

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231
BOX CONTINUATION

Dear Sir:

Please amend the application as follows.

IN THE CLAIMS

Please cancel claims 16-27, 30 and 31 without prejudice.

Please amend the following claims:

34. (Amended) In combination:

an aerosolization chamber for receiving an aerosol from a source of aerosol medication, the aerosolization chamber having an exit end;

a mask having an upstream end connected to the exit end of the aerosolization chamber;

a ring at the upstream end of the mask;

a one-way valve near the exit end of the aerosolization chamber and located in a first opening into the mask, the one-way valve preventing backflow into the aerosolization chamber; and

a second valve located in a second opening adjacent the first opening into the mask, the second valve operative to prevent air flow through the second opening upon patient inhalation but which permits air flow through the second opening upon exhalation into the mask so as to permit a patient wearing the mask to exhale air through the second opening, wherein the second valve is integrally molded with the remainder of the mask.

Please add the following claims:

15. In combination:

an aerosolization chamber for receiving an aerosol from a source of aerosol medication, said aerosolization chamber having an exit end with a first valve to prevent flow into said aerosolization chamber from said exit end; and

a mask having an inlet connected to the exit end of the aerosolization chamber, wherein said mask has minimal dead space inside yet provides efficient inhalation and exhalation flow paths that purge said mask of exhaled air;

and further wherein said mask provides a short exhalation flow path comprised of a second valve located in an opening adjacent said inlet and into said mask, said second valve adapted for positioning directly adjacent the nostrils of the nose, said second valve adapted

to permit air flow through said opening upon exhalation into said mask so as to permit a patient wearing said mask to exhale air through said opening, and

to prevent air flow through said opening upon patient inhalation;

and further wherein said first valve in said exit end of said aerosolization chamber permits flow from said aerosolization chamber into said mask, but not vice versa.

28. The invention of Claim 16 wherein said mask is comprised of a first frustoconical portion of rather shallow taper and a second frustoconical portion of greater taper, said second frustoconical portion being downstream of said first portion.

29. The invention of Claim 16 wherein said mask is comprised of:

a first frustoconical portion of shallow taper;
a second frustoconical portion of greater taper located downstream of said first frustoconical portion; and
a nosepiece extending from end to end of said second frustoconical portion, and wherein said second frustoconical portion opens radially into said nosepiece.

32. In combination:

an aerosolization chamber for receiving an aerosol from a source of aerosol medication said aerosolization chamber having an exit end;
a mask having an upstream end connected to the exit end of the aerosolization chamber, wherein said mask is comprised of a first frustoconical portion of shallow taper and a second frustoconical portion of greater taper than said first frustoconical portion;
a one-way valve near the exit end of the aerosolization chamber and located in a first opening into said mask, said one-way valve preventing backflow into the aerosolization chamber; and
a second valve located in a second opening adjacent said first opening into said mask, said second valve operative to prevent air flow through said second opening upon patient inhalation but which permits air flow through said second opening upon exhalation into said mask so as to permit a patient wearing said mask to exhale air through said second opening.

33. The invention of Claim 32 further comprising:

a nosepiece extending end to end of said second frustoconical portion.

34. In combination:

an aerosolization chamber for receiving an aerosol from a source of aerosol medication, said aerosolization chamber having an exit end;
a mask having an upstream end connected to the exit end of the aerosolization chamber;
a ring at said upstream end of the mask;

a one-way valve near the exit end of the aerosolization chamber and located in a first opening into said mask, said one-way valve preventing backflow into the aerosolization chamber; and

a second valve located in a second opening adjacent said first opening into said mask, said second valve operative to prevent air flow through said second opening upon patient inhalation but which permits air flow through said second opening upon exhalation into said mask so as to permit a patient wearing said mask to exhale air through said second opening.

35. The invention of Claim 34 wherein said ring is approximately 1.4 inches.

36. The invention of Claim 34 wherein said second valve comprises a circular head.

37. The invention of Claim 34 wherein said second valve is convex on an outer surface and concave on an inner surface.

38. The invention of Claim 34 wherein said second valve includes a valve head having an undersurface which is flattened against a flat front of a wall at said upstream end.

39. The invention of Claim 34 wherein said second valve is integrally molded with remainder of mask.

40. The invention of Claim 34 wherein said second valve has a slit that bows out.

41. The invention of Claim 34 wherein said mask is just over three inches in diameter across a rear thereof.

42. The invention of Claim 34 wherein said mask is just over 2 inches from a rear open end to said ring.

43. In combination:

an aerosolization chamber for receiving an aerosol from a source of aerosol medication, the aerosolization chamber having an exit end;

a mask having an upstream end connected to the exit end of the aerosolization chamber;

wherein the mask is comprised of:

a first frustoconical portion of a first taper;

a second frustoconical portion of a second taper located downstream of the first frustoconical portion, the second frustoconical portion comprises a majority of the mask, the second frustoconical portion adjacent the first frustoconical portion, the second frustoconical portion comprising a material that is stiffer than the material of the first frustoconical portion;

a nosepiece extending from the second frustoconical portion, and wherein the second frustoconical portion opens radially into the nosepiece;

a wall at the downstream end of the frustoconical portion;

a one-way valve near the exit end of the aerosolization chamber and located in an opening in the mask, the one-way valve preventing backflow into the aerosolization chamber, the one-way valve relative to an axis radially through the first frustoconical portion; and

a second valve located in an opening in the wall, the second valve operative to prevent air flow through the opening upon patient inhalation but which permits air flow through the opening upon exhalation into the mask so as to permit a patient wearing the mask to exhale air through the opening, the second valve having a valve flap, the valve flap comprised of the material of the second frustoconical portion.

44. In combination:

an aerosolization chamber for receiving an aerosol from a source of aerosol medication, the aerosolization chamber having an exit end;

a mask having an upstream end connected to the exit end of the aerosolization chamber;

wherein the mask is comprised of:

a frustoconical portion having a taper, the frustoconical portion associated with the exit end;

a nosepiece extending from end to end of the frustoconical portion, and wherein the frustoconical portion opens radially into the nosepiece;

a one-way valve near the exit end of the aerosolization chamber and located in an opening in the mask, the one-way valve preventing backflow into the aerosolization chamber; and

a vertical valve formed in the upstream end of the frustoconical portion, the vertical valve operative to prevent air flow through the opening upon patient inhalation but which permits air flow through the opening upon exhalation into the mask so as to permit a patient wearing the mask to exhale air through the opening.

IN THE SPECIFICATION

On page 1, immediately after the title please add -- This is a continuation of U.S. Serial Number 08/842,956, filed April 25, 1997, claiming priority of U.S. Serial No. 08/270,752, filed on July 5, 1994, which applications are hereby incorporated by reference. --

REMARKS

The specification and claims of this continuation application of U.S. Serial Number 08/842,956, filed April 25, 1997, claiming priority of U.S. Serial No. 08/270,752, filed on July 5, 1994 are amended by this Preliminary Amendment. This continuation application is being filed during the co-pendency of U.S. Serial Number 08/842,956 filed April 25, 1997, which has received a Notice of Allowability dated August 10, 1999.

In U.S. Serial No. 08/842,956, the Examiner indicated that claims 16-27, 30 and 31 are allowable. As such, these claims have been cancelled from the present continuation application. Applicant requests that remaining claims 15, 28-29, and 32-42, which were cancelled in the parent application, U.S. Serial No. 08/842,956, be acted upon in the present continuation application.

Claim 34 has been amended in this application. In the Office Action of January 4, 1999 in U.S. Serial No. 08/842,956, the Examiner rejected "[c]laims 16, 17, 22-27, 30, 34, 36, and 38 under 35 U.S.C. § 102(b) as being clearly anticipated by Schaefer." Claims 16, 17, 22-27, and 30 have been canceled in this application and therefore their rejection has been rendered moot in this continuing application. Independent claim 34 has been amended to include the limitations of claim 39 of U.S. Serial No. 08/842,956. The Examiner did not reject claim 39 under 35 U.S.C. § 102(b) in the parent application. As this element is novel over the cited reference and has been incorporated into amended claim 34, amended independent claim 34, and any claims dependent therefrom, is also novel. Therefore, applicant respectfully asserts that the Examiner's rejection of claim 34 has been successfully overcome and requests further action commensurate thereon.

In the Office Action of January 4, 1999 in U.S. Serial No. 08/842,956, the Examiner rejected claim 39 under 35 U.S.C. § 103(a) as being unpatentable over Schaefer in view of Katz et al and Booharin. Applicant submits that the subject matter of these claims is not obvious over this combination of references because the Examiner has provided no motivation for making this combination, as required by MPEP 2142-2144. These sections of the MPEP specifically establish the requirement that there must be a suggestion or motivation to modify the cited references to support a rejection for obviousness. As stated in the MPEP:

"[o]bviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art." (MPEP 2143.01, quoting from *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q. 2d 1596 (Fed. Cir. 1988).

Further, MPEP 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990 :

"[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." (emphasis in the original).

These MPEP sections are in accord with numerous well-established precedents. *In re Geiger*, 815 F. 2d 686, 2 U.S. P. Q. 2d 1271 (Fed. Cir. 1987); *N.V. Akzo v. E.I. du Pont de Nemours*, 810 F.2d 1148, 1 U.S. P.Q. 2d 1704 (Fed. Cir 1987); *In re Farrell*, 853 F.2d 894, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988).

Furthermore, the Applicant respectfully asserts that the combination of Booharin and Katz et al in view of Schaefer is improper. The Examiner states that Schaefer fails to disclose the exhalation valve of the present invention. Booharin and Katz et al are directed to gas masks constructed so as to eliminate fogging of the eye lenses of the masks. One skilled in the art of exhalation valves for delivery of an aerosolized medicament would not refer or look to a non-analogous art directed to improvements in gas masks. See MPEP 21-41.01(a); *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). Consequently, the combination of Booharin and Katz et al. in view of Schaefer is misapplied. Therefore, the Applicant respectfully asserts that claim 39 is unobvious over Booharin and Katz et al. in view of Schaefer.

Additionally, in the present case, the Examiner combined Katz et al. and Booharin with Schaefer. Arguably at best, Schaefer discloses an aerosolization chamber as claimed in the present invention. Further, one skilled in the art would not look to Booharin and Katz et al. to teach or suggest an exhalation valve for use in conjunction with an aerosolization chamber as claimed in claim 34. Further, there is no teaching or suggestion, either implicitly or explicitly, to combine these references. Therefore, Applicant respectfully submits that claim 34 is not rendered obvious.

Applicant incorporates herein the remarks of the Response of April 5, 1999 in U.S. Serial No. 08/842,956.

CONCLUSION

In view of the amendments and remarks above, Applicant respectfully submits that all of the pending claims are in condition for allowance and seeks an early allowance thereof. If for any reason the Examiner is unable to allow the application in the next Office Action and believes that an interview would be helpful

to resolve any remaining issues, the Examiner is respectfully requested to contact the undersigned attorneys at (312) 321-4217.

Respectfully submitted,

A handwritten signature in cursive script, reading "Vita Conforti", written over a horizontal line.

Vita G. Conforti

Registration No. 39,639

Attorney for Applicants

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EXHALATION VALVE

Background of the Invention

Breathing problems due to allergies, asthma, etc. are widespread. It is known that such problems can be helped with inhalation of appropriate medication, such as a beta agonist. Small cartridges containing such medication are provided. Each cartridge has a valve which when activated dispenses a predetermined quantity of medication as a spray. Such devices are known as metered dose inhalers (MDI). Such metered dose inhalers are rather inefficient in delivering the medication to the patient. It is known that provision of some sort of an inhalation chamber between the MDI and the patient's mouth materially improves delivery to the patient. One such device that has met rather considerable commercial success is disclosed and claimed in Nowacki et al U.S. Patent 4,470,412.

Further problems are encountered with delivery of antiasthmatic medication to children. With adults in otherwise reasonably good health the patient generally can be relied upon to handle the matter himself, or to communicate with a healthcare provider. However, children, particularly infants, cannot readily follow directions, and often cannot communicate with a healthcare provider. Accordingly, efforts have been made so that a healthcare provider can readily observe whether a small child or infant is properly inhaling and exhaling, and thereby taking in the necessary medication. Two inhalers for this purpose are shown in Nowacki et al U.S. Patent 4,809,022, and in Nowacki et al U.S. Patent

4,832,015. It has been found in practice that anxious mothers often produce false readings with infants and other small children, and it further has been found that producing requisite plastic moldings at a commercially acceptable cost has been difficult.

In the last two U.S. patents noted above a small mask is attached to the exit end of the aerosolizing chamber to engage an infant's face to ensure proper movement of the vaporized or aerosolized medication from the chamber into the patient's mouth and nose. Such mask is generally made of a plastic or rubber material. In the first of these two patents a whistle is provided that operates upon inhalation or exhalation of the patient (or both) so that a sound will be produced that can be observed by a healthcare provider. However, the sound is not very loud, and is sometimes indiscernable in conditions of relatively high ambient noise levels. In the second of such two patents a bubble of thinner material is formed integral with the mask, and is intended to move in and out with inhalation and exhalation. The bubble must be thin enough to flex readily, but not so thin as to tear or otherwise fracture. Molding of the mask to produce a relatively thick mask, and the extremely thin integral bubble is difficult.

It will be recognized that a person who is elderly, or who is sick, or who is in some manner incapacitated may present many of the same problems of communicating with or being observed by a healthcare provider as with infants.

Objects of the Present Invention

In accordance with the principles of the present invention it is an object thereof to provide a mask for inhalation of medication, such as asthmatic medication, which has an exhalation valve that is closed upon rest or upon inhalation, but which

discernably moves to an open position upon exhalation by the patient.

It is a further object of the present invention to provide an exhalation valve in a medication mask which is closed at rest or on inhalation, and which is readily observable as being closed, and which positively opens in a readily discernable manner upon exhalation, which valve is simple and positive, and readily produced at low cost.

In carrying out the principles of the present invention a pediatric mask is provided such as in U.S. Patents 4,809,692 and 4,832,015 mentioned above. The preferred material for molding such mask is silicone rubber. This material can be autoclaved for sterilization, and is well accepted by the medical profession and governmental bodies that might have to approve of the mask. The mask is translucent, and hence it is possible to see at least a limited distance therethrough. In a preferred form of the invention a valve member is also molded of silicone rubber and is assembled with the balance of the mask by means of an insert and pull operation, with no added fastener being required. In a second form of the invention the valve is molded as an integral part of the mask. Other types of observable one-way air valves are contemplated but the two herein are sufficient for illustration.

The Drawings

The invention will best be understood with reference to the following specification when taken in connection with the accompanying drawings wherein:

Fig. 1 is a side view of a preferred form of mask having an exhalation valve therein;

Fig. 2 is a view taken from the right side of Fig. 1,

comprising an end view of the mask;

Fig. 3 is a view similar to Fig. 2 but before installation of the valve;

Fig. 4 is a sectional view of the valve and a portion of the mask on an enlarged scale as taken along the line 4-4 in Fig. 3;

Fig. 5 is an end view of the valve and adjacent portion of the mask as taken from the right end of Fig. 4 on a further enlarged scale;

Fig. 6 is a perspective view of the mask;

Fig. 7 is a side view on an enlarged scale of the closure member of the valve;

Fig. 8 is a view of the valve closure member as taken from the right side of Fig. 7;

Fig. 9 is an axial sectional view of a second embodiment of the mask;

Fig. 10 is a perspective view of the mask of Fig. 9 as taken from above and the front end:

Fig. 11 is a fragmentary right end view of the valve portion of the mask of Fig. 9 as taken substantially along the line 11-11 in Fig. 9; and

Fig. 12 is a top view of the mask of Fig. 9.

Detailed Description of the Illustrated Embodiments

Turning now to the drawings in greater particularity, and first to Figs. 1-8, there will be seen a cylindrical aerosolization chamber 20 (Fig. 1). This chamber is only shown in part, since it may be the same as that shown in Nowacki et al 4,470,412 or in Foley et al 5,012,803, except that the exhalation ports in the aerosolization chamber are deleted. The aerosolization chamber is molded of a semi-rigid plastic, and the exit end thereof is

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inserted within a gripping ring 22 at the upstream end of a mask 24 molded of suitable material which is sufficiently pliable to conform to an infant's face. A preferred material is translucent silicone rubber. The mask includes a first frustoconical portion 26 of rather shallow taper integral with the ring 22, and a second or downstream portion 28 of frustoconical shape of greater taper. The outer edge 30 (the left edge in Fig. 1) is open, and air and medication flow through the chamber 20 and into the mask as indicated by the arrows 33. The inner surface of the ring 22 is cylindrical and is of small enough diameter to grip the rear end of the aerosolization chamber 20. The mask is circular in outline or cross section, with the exception of a nosepiece 32 and a valve 34, both of which are formed integral with the mask save for an operating or closure member in the valve to be noted hereinafter. The nosepiece 32 extends substantially from end to end of the rearward or portion of greater taper 28, with the frustoconical portion 28 opening radially into the nosepiece. The nosepiece has an outer edge 36 substantially parallel to the corresponding outer surface of the frustoconical portion 28 adjacent to the nosepiece. The nosepiece is substantially an inverted V having legs 38 joined together by an arcuate portion 40 which includes the outer edge 36. At the forward or upstream end the lowest portion ^{of nosepiece} 32 is terminated by a vertical wall 42. (The use of "upstream" is intended to refer relative to the air and medication movement through the aerosolization chamber 20 and into the mask 24, as indicated by the arrows 33.)

Forwardly or upstream of the wall 42 there is a boxlike housing 44 extending outwardly from the mask body and closed off therefrom by a portion of the first frustoconical portion 26 and

forming a floor 46 to the valve body or housing. Walls 48 extend substantially vertically outwardly from the frustoconical portion 26, and taper inwardly at 50 to a flat roof 52. The upstream end of the valve body 44 is open at 54, and the downstream end of the housing is integrally sealed to the wall 42.

The wall 42 is provided with a small central opening 56 and with a pair of arcuate openings 58 concentric with and spaced horizontally from the smaller central opening 56.

A valve closure member 60 is seen best in Figs. 7 and 8, and includes a circular head 62. The head is molded so as to be convex on the outer surface 64, and concave on the undersurface 66. Inwardly or rearwardly from the convex inner surface 66 a stem 68 extends rearwardly along the axis of the head 62. The stem somewhat closer to the undersurface 66 than to the outer end 70 of the stem is provided with an integral annular ring or enlargement 72 having a semicircular cross section.

The diameter of the stem 68 is exactly the same as the diameter of the central hole 56, and the distance from the undersurface 66 of the head 62 to the confronting edge of the enlargement 72 is the same as, or very slightly less than the thickness of the wall 42. Accordingly, to assemble the valve head 60 with the mask the end of the stem 70 is pushed through the hole 56 from the upstream surface of the wall 42. Since the enlargement 72 is spaced closer to the undersurface 66 of the valve head than it is to the outer end 70 of the stem, the outer end 70 projects through the wall 42 by the time the enlargement 72 engages the front surface of the wall. The stem adjacent the outer end 70 thus can be grasped and pulled through the hole 56. Stretching of the stem 68 somewhat reduces its diameter. The enlargement 72 is

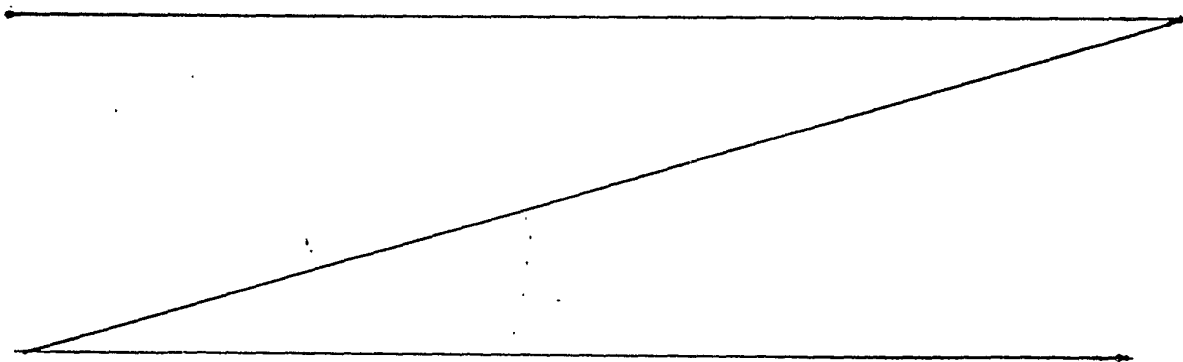
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squashed inwardly by the hole 56, while the hole 56 is somewhat enlarged on a temporary basis by the enlargement 72. Thus, the enlargement 72 moves through the wall to abut the rear surface thereof as shown in Fig. 4 to hold the valve member 60 in place. The undersurface 66 of the valve head 62 is flattened against the flat front surface of the wall 42 as shown in Fig. 4. Accordingly, no air can pass through the valve structure from the upstream end (the right end in Fig. 4, for example) into the mask. However, when the infant exhales the pressure within the mask is increased. This increased pressure cannot cause backflow into the aerosolization chamber 20 due to the provision of a one-way valve near the exit end (downstream end) of the aerosolization chamber. However, the air pressure passes air through the arcuate openings 58, flexing the head 62 away from the arcuate openings 58 as shown in broken lines in Fig. 4, thereby permitting exhalation by the infant. Subsequent rest or inhalation by the infant returns the interior of the mask to ambient air pressure or below, and the valve head 62 again flattens against the wall 42.

Flexure of the valve head 62 over the openings 58 is somewhat as if there were two doors pivoted about one or more vertical axes passing through or adjacent to the smaller hole 56. Such movement readily can be seen by a healthcare provider (or the infant's mother) looking into the valve body through the open end 54, or looking through the translucent walls 48, 52 of the valve body. Thus, observation of exhalation is positively assured, and there cannot be exhalation unless there is first inhalation. Thus, it is readily ascertained that the infant is breathing and inhaling the desired medication. All of the parts are large enough to resist rupture or tearing without difficulty, and are readily molded.

Installation of the valve member is quick and simple, and adds very little to the overall cost of the mask. No particular close tolerances must be held to provide an integral part of the mask that must flex as has been done in at least some of the prior art.

A modification of the invention is shown in Figs. 9-12. Many of the parts are similar to those heretofore shown and described, and are identified by the use of similar numerals with the addition of the suffix a to avoid repetition of disclosure. The mask 24a is in most respects substantially the same as that disclosed and claimed in the aforesaid U.S. Patent 4,832,015, but omits the flexible bubble previously used as an indicator of breathing by an infant.



An exhalation valve 34a is molded integrally with the remainder of the mask. It opens at its rear into the nosepiece 40a, and is of the type known as a duckbill valve. It includes a forwardly extending generally cylindrical section 76 tapering inwardly at a thinning frustoconical section 78 to a reduced diameter cylindrical section 80. The duckbill valve 34a then steps inwardly at 82 to a thinned forwardly projecting bill 84 terminating at a flat nose 86 having a slit 88 (Fig. 11) extending horizontally across it. The slit 88 is normally closed as shown by the solid line in Fig. 11. Upon inhalation pressure within the mask is reduced below ambient pressure, and the thinned

side portions 84 adjacent the flat nose 86 tend to come together further to close the valve to prevent ingress of air. However, upon exhalation the slit 88 bows outwardly as shown by the broken lines 90 in Figs. 9 and 11, whereby air readily exits from the exhalation valve 34a.

Both forms of the invention as herein shown and described positively prevent ingress of air through the exhalation valve, and afford egress thereof at very little pressure above ambient pressure, less than 0.50 inch of water. Since the second form of the invention in Figs. 9-12 has the entire valve formed as an integral part of the mask no assembly step is required in producing the mask. However, molding is somewhat more difficult. In the first and preferred form of the mask as shown in Figs. 1-8 the assembly step is extremely simple, and does not require much additional labor. Molding is greatly simplified. As has been noted earlier the enlargement 72 on the valve stem 68 avoids the necessity of any separate fastener to hold the umbrella-like valve in installed position, yet is easily moved to installed position. The valve in the first embodiment also opens readily on exhalation with less than 0.50 inch of water internal pressure above ambient, and provides positive closure against entrance of air upon inhalation. It will be appreciated that it is not desired to have air enter upon inhalation as it would dilute the medication being brought in from the aerosolization chamber 20. Exit of air through the two openings or ports 58 provides for passage of a generous amount of exhaled air.

The mask and valve are intended primarily for use with an infant or young child, and in both instances the opening of the valve is readily seen by a healthcare provider, either professional

or a parent.

The mask is intended primarily for use with infants and small or young children. Approximate dimensions for the mask are just over 3 inches diameter across the rear, open end 30 and just over two inches from this rear open end 30 to the front of the ring 22 gripping the aerosolization chamber. The inside diameter of the ring 22a is approximately 1.4 inches, while the wall thickness is on the order of .08 inch. The diameter of the valve head 62 is .440 inch and the thickness is .015 inch. The length of the valve stem 68 is .280 inch from the underside of the head to the end 70. The radius of the valve stem is .040 inch, except at the enlargement 72 where the outside diameter is .070.. The radius of the enlargement (in axial section of the stem) is .015 inch.

As noted earlier, the valve opens with a very slight air pressure. An inhalation pressure of 0.5 inch of water below ambient pressure is sufficient to open the valve. Furthermore, the valve is recessed sufficiently as to avoid damage by searching fingers. Damage to the valve that would inhibit operation is thereby positively avoided. The valve is recessed by at least the diameter of the valve.

The mask fits very closely to the face, and the nosepiece adds little volume. Thus the total volume of the mask is not very great. Accordingly, the medication in the mask, including the nosepiece, is a minimum. The amount of air exhaled is not very great, and previously inhaled air with medication stays for inhalation by the patient. This is an important feature of the present invention. Air held in the mask by the inhalation valve (provided by the valve in the aerosolization chamber), and by the

exhalation valve in the mask is retained for a second inhalation. No medication is wasted. With each breath the medication laden air is refreshed for further inhalation by the patient, and is reinforced with the addition of fresh medication laden air.

With every breath, fresh air laden with medication enters the mask from the aerosolization chamber. This air enters the mask adjacent the mouth and nose. There is very little dead space within the mask. Thus substantially all of the medication laden air is available for inhalation. The medication laden air is retained within the mask by the inlet and outlet valves is available for further inhalation. The amount expelled from the mask by exhalation is just equal to fresh air with medication drawn into the air by inhalation, so that the medication is held close to the patient's face for subsequent inhalation. Very little is wasted.

As noted earlier there are some adult patients who must inhale medication, but are for one reason or another incapable of handling an aerosolization chamber and MDI personally. A similar mask of slightly larger size would be in order for such patients, with a healthcare provider or friend to observe the opening of the valve upon exhalation, and closure upon inhalation.

Particularly in the preferred form of the invention the exhalation valve is located directly adjacent the nostrils, and thereby forms a short path for exhalation from the mask.

The specific embodiments of the invention as herein shown and described are for illustrative purposes only. Various changes in structure will no doubt occur to those skilled in the art, and will be understood as forming a part of the present invention insofar as they fall within the spirit and scope of the appended claims.

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The invention is claimed as follows:

1. A mask for the inhalation of medication by a human being, said mask being molded of plastic material or the like having an interior and a central through opening including an open front portion adapted to receive a hollow body having air with medication dispersed therein, a sidewall expanding outwardly from said front portion to a rear portion adapted to fit sealingly on a human face and covering the mouth and nose, said sidewall including a tunnel-like extension projecting outwardly of said sidewall and adapted to overlie a nose, said extension extending substantially from said rear portion toward said front portion and having a front end terminating short of said front portion of said mask, and a normally closed one-way valve adjacent said front end of said extension and communicating on one side inwardly of said mask into said extension and on the other side communicating outwardly of said mask to outside air, said exhalation valve opening on exhalation to pass exhaled air from said mask and closing in the absence of exhaled air to prevent entry of outside air.
2. A mask as set forth in claim 1 wherein said valve is positioned in its entirety short of said front portion of said mask.
3. A mask as set forth in claim 1 and further including a transverse wall adjacent the end of said nose receiving extension relatively toward the mask open front portion, said valve being through said transverse wall.

4. A mask as set forth in claim 3 wherein said valve includes an exhalation opening through said transverse wall and an adjacent anchor opening through said transverse wall, said valve including a valve closure element comprising a head and an integral stem of plastic material, said head normally covering said exhalation opening relatively toward the exterior of said mask and said stem extending into said anchor opening to anchor said head, said head resiliently moving at least in part from said exhalation opening upon exhalation.

5. A mask as set forth in claim 4 wherein said stem extends entirely through said transverse wall and has an enlargement thereon engaging said transverse wall opposite to said valve member head.

6. A mask as set forth in claim 6 wherein said head is resilient and flexes away from said exhalation opening upon exhalation.

7. A mask as set forth in claim 6 wherein there are two exhalation openings through said transverse wall and lying on opposite sides of said anchor opening, said head having an undersurface inherently concave and pulled substantially flat by said stem, said head flexing outwardly upon exhalation.

8. A mask as set forth in claim 1 wherein said exhalation valve comprises a duckbill valve extending from said front end of said extension toward said front end portion of said mask but terminating short of said front end portion.

9. A mask for inhalation of medication by a human being, said mask being molded of plastic material or the like having an interior and a through opening including a portion adapted to receive a hollow body having air with medication dispersed therein, a sidewall expanding outwardly from said front portion to a rear portion adapted to fit sealingly on a human face and covering the mouth and nose, and a normally closed one-way exhalation valve in the front portion of said mask, said valve including a passageway through said front portion and having a transverse wall comprising a valve seat, said transverse wall having an exhalation opening therethrough and an adjacent anchor opening through said transverse wall, said valve including a valve closure element comprising a head and an integral stem of plastic material, said head normally covering said exhalation opening and disposed relatively toward the exterior of said mask and said stem extending into said anchor opening to anchor said head, said head resiliently moving at least in part from said exhalation opening upon exhalation.

10. A mask as set forth in claim 9 wherein said stem extends entirely through said transverse wall and has an enlargement thereon engaging said transverse wall opposite to said valve member head.

11. A mask for the inhalation of medication by a human being, said mask being molded of plastic material or the like having an interior and a through opening including an open front portion receiving a hollow body having air with medication dispersed therein and providing a one-way inhalation valve for said mask, said inhalation valve normally being closed and opening upon inhalation, a sidewall expanding outwardly from said front portion to a rear portion adapted to fit sealingly on a human face and covering the mouth and nose, said sidewall including a forward extension projecting outwardly of said sidewall and adapted to overlie a nose, said extension extending substantially from said rear portion toward said front portion, and a normally closed one-way exhalation valve adjacent said extension, said exhalation valve opening on exhalation to pass exhaled air from said mask and closing in the absence of exhaled air to prevent entry of outside air, said inhalation valve and said exhalation valve holding air with medication in said mask for most effective utilization of said medication.

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12. A mask for the inhalation of medication by a human being, said mask being molded of a plastic material or the like having an interior and a central through opening including an open front portion for receiving a hollow body having aerosol with medication dispersed therein, a substantially frusto-conical sidewall expanding outwardly from said front portion to a rear portion adapted to fit sealingly on a human face and covering the mouth and nose with a minimum of dead space holding exhaled air in said mask, including a tunnel-like extension projecting outwardly of said sidewall and adapted to overlie a human nose, said extension extending substantially from said rear portion toward said front portion and having a front end terminating short of said front portion of said mask, and a normally closed one-way valve adjacent said front end of said extension for subsequent alignment with the nostril of a human nose and communication on one side inwardly of said mask into said extension and on the other side communicating outwardly of said mask to outside air, said exhalation valve having a quick acting lightweight valve extending outwardly from a central stem to provide a light weight seal on the outside edge of said valve providing a minimum resistance to exhaled air and quick response to exhalation of air and minimizing the amount of exhaled air retained by said mask to reduce the work of breathing by a human being, said exhalation valve closing in the absence of exhaled air to prevent entry of outside air.

13. A mask as set forth in claim 12 wherein said valve is positioned in its entirety short of said mask extension to reduce access to prying fingers.

14. A mask as set forth in claim 13 and further including a transverse wall adjacent the end of said nose receiving extension relatively toward the mask open front portion, an exhalation opening through said transverse wall, said valve including a valve closure member.

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ABSTRACT OF THE DISCLOSURE

A mask is provided for the inhalation of medication, such as asthmatic medication. The mask is molded of a resilient plastic or rubber material and has a central through opening and includes an open front portion adapted to receive an aerosolization chamber which receives medication from a metered dose inhaler. A sidewall expands outwardly from the open front portion and is adapted to fit sealingly on a face covering the mouth and nose. The sidewall is provided with an extension to accommodate the nose. A one-way exhalation valve is provided in the mask, preferably at the far end of the nose accommodating extension for conveying exhaled air to the outside, and preventing entrance of outside air therethrough into said mask.

FIG. 1

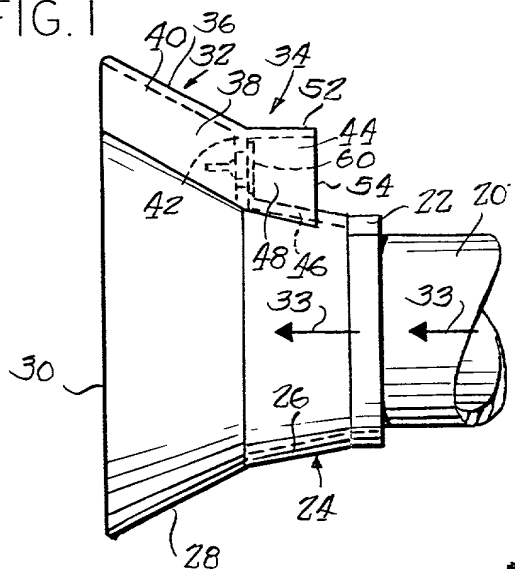


FIG. 2

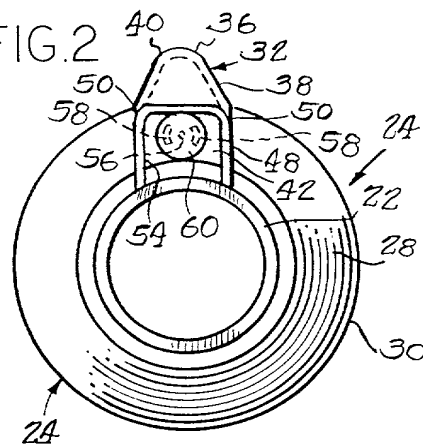


FIG. 4

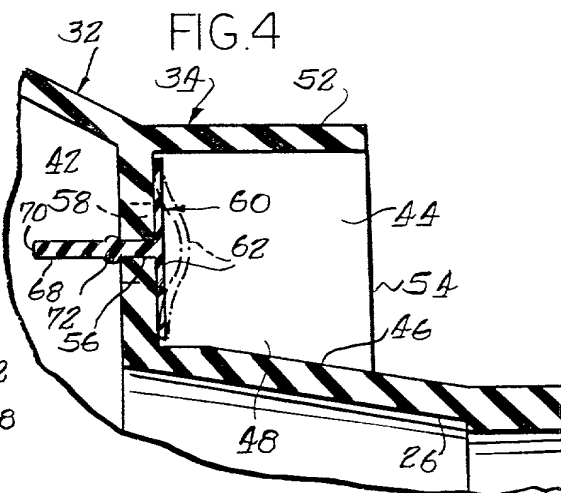


FIG. 3

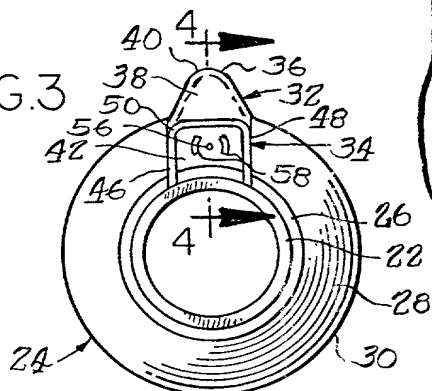


FIG. 5

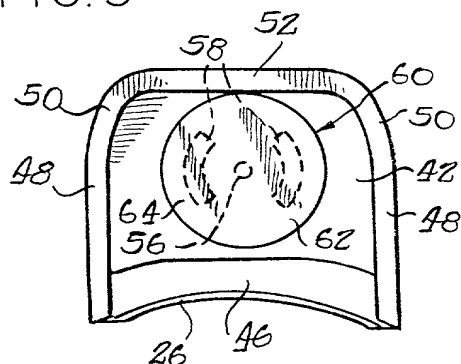


FIG. 6

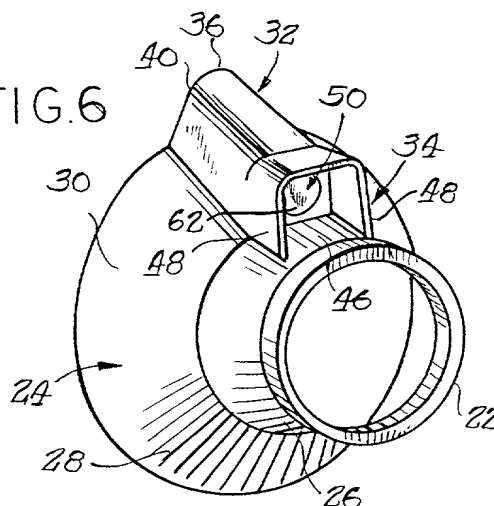


FIG. 8

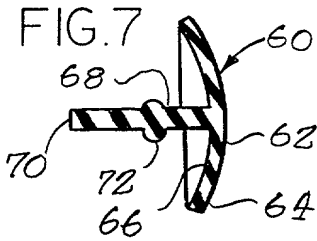
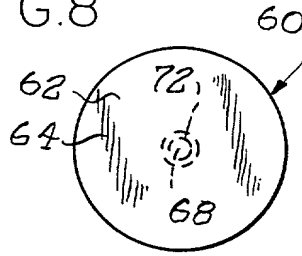


FIG. 9

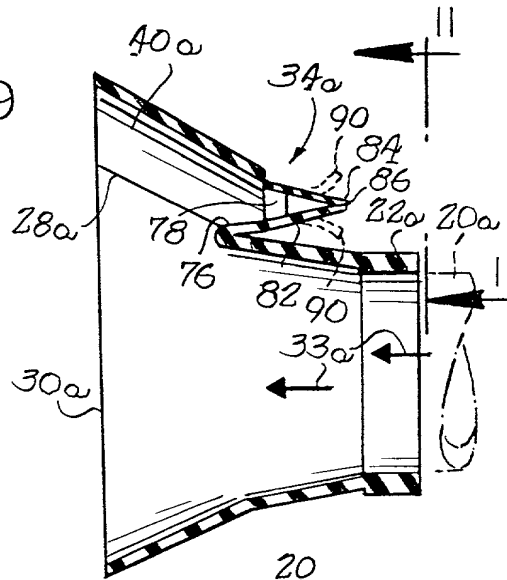


FIG. 9a

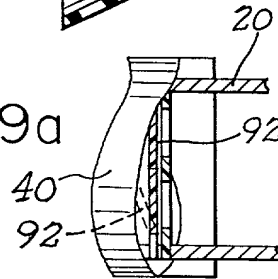


FIG. 11

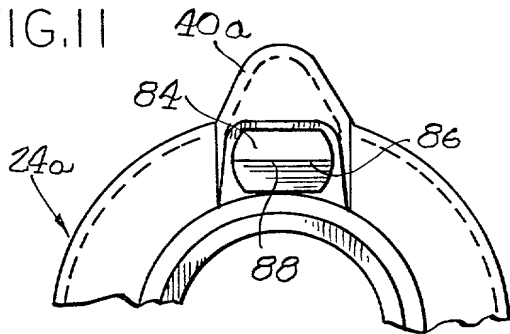
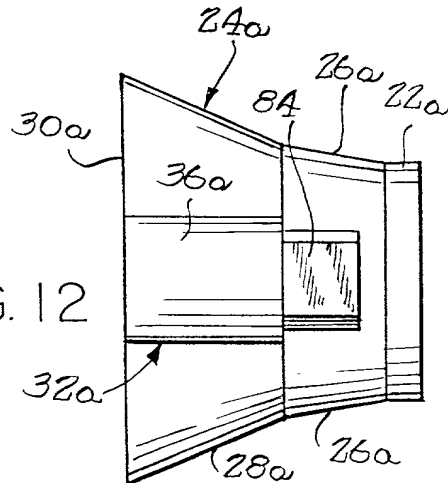


FIG. 12



DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled EXHALATION VALVE, the specification of which

(check one) ☐ is attached hereto.
☐ was filed on _____ as
 Application Serial No. _____
 and was amended on _____
 (if applicable)

filed 11/09/92

This application is a continuation-in-part of application 07/973,280/
 I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes	<input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing Date)	(Status) (patented, pending, abandoned)
07/973,280	11/09/92	finally rejected (on Appeal)
_____	_____	_____
_____	_____	_____

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Robert M. Wolters, Reg. No. 17,316
8840 Reigate Lane, Raleigh, NC 27603

SEND CORRESPONDENCE TO: Robert M. Wolters

DIRECT TELEPHONE CALLS TO: (919) 779-5138

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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 Second Inventor's signature Robert Morton

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(Supply similar information and signature for third and subsequent joint inventors.)

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled EXHALATION VALVE, the specification of which:

 is attached hereto.

 / was filed on July 5, 1994 as Application Serial No. 08/270,752

 / and was amended on July 5, 1994 (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, § 1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)Priority Claimed

(Number)	(Country)	(Day/Month/Year Filed)	Yes	No
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I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

<u>07/273,280</u> (Application Serial No.)	<u>November 9, 1992</u> (Filing Date)	<u>Abandoned</u> (Status-patented, pending, abandoned)
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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Full name of sole or first inventor
Residence
Citizenship
Post Office Address

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